## UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

	x	
GLADYS MENSING	:	
Plaintiff	:	Civil No. 07-3919 (DWF/SRN)
v.	:	AFFIDAVIT OF PHILIP
WYETH, INC. et al.,	:	ERICKSON IN SUPPORT OF MOTION FOR
D.C. 1.	:	SUMMARY JUDGMENT
Defendants.	: x	
COMMONWEALTH OF PENNSYLVA	NIA )	
COMMONWEALTHOFFERINGILVA	) ss.:	

Philip Erickson, being duly sworn, deposes and says:

COUNTY OF MONTGOMERY

1. I am Senior Director, Regulatory Affairs of Teva Pharmaceuticals USA, Inc. ("Teva"). I am fully familiar with the facts recited herein based upon my personal knowledge and the discharge of my duties in the ordinary course, and I make this Affidavit in support of the Motion for Summary Judgment of Teva and UDL Laboratories, Inc. ("UDL") in this action.

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2. Teva is the owner of FDA-approved Abbreviated New Drug Applications ("ANDA") for the prescription drug metoclopramide, pursuant to which it has manufactured and sold metoclopramide in dosage form. Teva has never submitted, held the rights to or owned a New Drug Application for any product in which metoclopramide was an active pharmaceutical ingredient. Accordingly, Teva has manufactured and sold exclusively generic metoclopramide products.

- 3. As the holder of an ANDA for metoclopramide, Teva was without discretion with respect to the content of its product labeling (package insert). Teva's package insert was required to conform to that of the FDA-approved labeling for the reference-listed drug Reglan®, but for the enumerated differences permitted by 28 C.F.R. § 314.94(a)(8)(iv), none of which are pertinent to warnings or safety information.
- 4. For a period of time, Teva and UDL were parties to a Supply and Distribution Agreement, pursuant to which UDL was to distribute, with its own trade dress labeling, metoclopramide manufactured by Teva under the authority of Teva's ANDA. Teva supplied UDL with language for the package insert to be included by UDL with such UDL-distributed metoclopramide, which package insert, being for an ANDA drug was also required to conform to that of the FDA-approved labeling for the reference-listed drug Reglan®, but for the enumerated differences permitted by 28 C.F.R. § 314.94(a)(8)(iv), none of which are pertinent to warnings or safety information. I have reviewed the UDL package insert current at the time UDL metoclopramide was allegedly dispensed to plaintiff Gladys Mensing, and conclude that it indeed conformed to that of the then-current package insert for Reglan (and for that matter Teva's), but for the permissible differences.

Further, Affiant sayeth naught.

s/ Philip Erickson	
Philip Erickson	
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	s/ Philip Erickson Philip Erickson

Sworn to before me this 3<sup>rd</sup> day of July, 2008.

s/ Gina M. Elton	
Notary Public	